CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be

- a) a guide for reporting for authors of RCTs,
- b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.

Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.

In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED). Please fill in these questions diligently. Information will not be copyedited, so please use

proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):

Eysenbach G, CONSORT-EHEALTH Group

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions

J Med Internet Res 2011;13(4):e126

URL: http://www.jmir.org/2011/4/e126/

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doi: 10.2196/jmir.1923 PMID: 22209829

* Required

Your name *

First Last

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Title of your manuscript *

Provide the (draft) title of your manuscript.

The Effects of a Web-based Tool for Parents of Children with Juvenile Idiopathic Arthritis: Randomised Controlled Trial.

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

WebParC (Web-based tool for parents of childr

Evalua	ated Version (if any)
e.g. "V1	", "Release 2017-03-01", "Version 2.0.27913"
Your a	nswer
Langi	uage(s) *
What la	nguage is the intervention/app in? If multiple languages are available, separate by comma (e.g. n, French")
Englisl	h
URL o	f your Intervention Website or App
	irect link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the nation is a DVD or hardware, you can also link to an Amazon page.
Your a	nswer
URL o	f an image/screenshot (optional)
Your a	nswer
Acces	ssibility *
Can an	enduser access the intervention presently?
O a	ccess is free and open
a	ccess only for special usergroups, not open
O a	ccess is open to everyone, but requires payment/subscription/in-app purchases
O a	pp/intervention no longer accessible
0 0	ther:

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

juvenile idiopathic arthritis

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Pediatric Inventory for Parents (PIP) measure

Secondary/other outcomes

Are there any other outcomes the intervention is expected to affect?

Anxiety; Depression; Self-efficacy; Effectiveness in managing child's healthcare; Satisfaction with healthcare; Child's health-related quality of life

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- as needed"
- Other:

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *
unknown / not evaluated
0-10%
O 11-20%
21-30%
31-40%
41-50%
51-60%
61-70%
71%-80%
81-90%
91-100%
Other: analysis to be reported in separate manuscript
Overall, was the app/intervention effective? *
yes: all primary outcomes were significantly better in intervention group vs control
partly: SOME primary outcomes were significantly better in intervention group vs control
on statistically significant difference between control and intervention
outcomes potentially harmful: control was significantly better than intervention in one or more
inconclusive: more research is needed
Other:

Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form)
not submitted yet - in early draft status
not submitted yet - in late draft status, just before submission
submitted to a journal but not reviewed yet
submitted to a journal and after receiving initial reviewer comments
submitted to a journal and accepted, but not published yet
O published
Other:
Journal *
Journal * If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")
If you already know where you will submit this paper (or if it is already submitted), please provide the
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") not submitted yet / unclear where I will submit this
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") not submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR)
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") not submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") ont submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth JMIR Serious Games
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") not submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth JMIR Serious Games JMIR Mental Health
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") not submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth JMIR Serious Games JMIR Mental Health JMIR Public Health
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") not submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth JMIR Serious Games JMIR Mental Health JMIR Public Health JMIR Formative Research

Is this a full powered effectiveness trial or a pilot/feasibility trial? *
O Pilot/feasibility
Fully powered
Manuscript tracking number *
If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)
on ms number (yet) / not (yet) submitted to / published in JMIR
Other: 29787
TITLE AND ABSTRACT
1a) TITLE: Identification as a randomized trial in the title
 1a) TITLE: Identification as a randomized trial in the title 1a) Does your paper address CONSORT item 1a? * I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")
1a) Does your paper address CONSORT item 1a? * I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under
1a) Does your paper address CONSORT item 1a? * I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

	1a-i) Identif	v the	mode	of	delivery	∕ in	the	title
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Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if Intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.

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subitem not at all important

Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The Effects of a Web-based Tool for Parents of Children with Juvenile Idiopathic Arthritis: Randomised Controlled Trial."

1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

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subitem not at all important OOOOO essential

Does your paper address subitem 1a-ii?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable - the intervention is fully web-based

1a-iii) Primary	condition /	or target	aroun	in the	title
10 111	<i>)</i>	y condition	or target	group	111 1110	uuc

Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes") Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

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subitem not at all important

essential

Does your paper address subitem 1a-iii? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The Effects of a Web-based Tool for Parents of Children with Juvenile Idiopathic Arthritis: Randomised Controlled Trial."

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-i? *

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The WebParC intervention consists of information about JIA and its treatment plus a toolkit, based on cognitive-behavioural therapy, to help parents develop skills to manage JIArelated issues."

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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subitem not at all important

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Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Objective: To evaluate the benefits of a web-based tool ("WebParC") for parents of children with recently diagnosed juvenile idiopathic arthritis (JIA)....They were randomised to the Intervention (WebParC access plus standard care) or the Control (standard care alone)...The WebParC intervention consists of information about JIA and its treatment plus a toolkit, based on cognitive-behavioural therapy, to help parents develop skills to manage JIA-related issues."

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or "unblinded" to indicated the level of blinding instead of "open", as "open" in web-based trials usually refers to "open access" (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important essential

Does your paper address subitem 1b-iii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Parents ... were recruited when they attended clinic with their child"; "The primary outcome was the self-report Pediatric Inventory for Parents"

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"A total of 203 'households' were randomised to the Intervention (n=100) or Control (n=103) arm. Follow-up assessments were completed by 133 (65.5%) at 4-months (60 Intervention, 73 Control) and 124 (61.1%) (58 Intervention, 66 Controls) at 12-months."

Adherence use is not reported - this manuscript reports the trial outcomes; another process evaluation manuscript is being prepared which will include a detailed analysis of the usage data

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

5 subitem not at all important essential

Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The WebParC website for parents of children with JIA reduced illness-related parenting stress."

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem	and the	type	of sy	vstem/	solution
	,		-,	· · ·	,	

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

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Does your paper address subitem 2a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is covered in the manuscript introduction section.

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

subitem not at all important essential

Does your paper address subitem 2a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is covered in the manuscript introduction section.

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Aim

To test that hypothesis that families provided with WebParC in addition to standard care would experience less illness-related parenting stress than those provided standard care alone. "

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Design

Multi-centre RCT."

"Randomisation was in a ratio of 1:1 to trial arms. Where both parents participated, they were randomised to the same trial arm (i.e. randomisation clustered by household)."

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"If the questionnaire was not returned, a member of the site research team called participants. This was a change to the protocol made part-way through the trial to enhance questionnaire return rates."

"Participants were sent a £5 gift voucher on return of each completed study questionnaire A protocol change was made part-way through the trial to enhance questionnaire return rates but was paid retrospectively to all participants."

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

3 subitem not at all important essential

Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

no changes were made to the intervention or comparator during the trial

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Research participants:

Parents attending rheumatology clinic appointments with their child, who met the following criteria:

Inclusion Criteria:

- Parent aged ≥18 years, with a child aged ≤12 years, newly diagnosed with JIA (within previous 6 months), according to internationally agreed criteria[13]. One or both parents could participate.
- Able to speak and read English.

Exclusion Criteria:

- Identifiable psychosis in parents
- Major problems with literacy making the questionnaire completion impossible
- Likely to be distressed by the study as judged by their child's rheumatologist."

4a-i) Computer / Internet lite	eracy					
Computer / Internet literacy is often a clarified.	an implicit	"de facto"	' eligibility	criterion -	this shoul	d be explicitly
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Parents were excluded if they had problems with literacy

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely webbased trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

5 subitem not at all important essential

Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Parents were invited to participate by their child's rheumatologist when attending a clinic appointment with their child."

"Intervention arm: In addition to standard care, those allocated to the intervention arm were given free unlimited password-protected access to the website."

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

3 subitem not at all important essential

Does your paper address subitem 4a-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Parents were invited to participate by their child's rheumatologist when attending a clinic appointment with their child. Interested parents had time to consider participation and opportunities to ask questions before providing written consent to site research staff. If their child with JIA was aged 8-12 years, the child's assent was obtained for their demographic and clinical data to be collected for the research."

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Parents were invited to participate by their child's rheumatologist when attending a clinic appointment with their child. Interested parents had time to consider participation and opportunities to ask questions before providing written consent to site research staff. If their child with JIA was aged 8-12 years, the child's assent was obtained for their demographic and clinical data to be collected for the research. After providing consent, participants were given baseline questionnaires to complete in clinic or at home and return to the trial co-ordinating centre (freepost envelope provided). A link to an online version of the questionnaire was also provided so parents could choose their preferred completion mode."

"At 4 and 12-months post-randomisation, the trial centre sent follow-up questionnaires both electronically and in hardcopy for participants to choose preferred completion method. Telephone and text reminders were sent if questionnaires were not returned within 2 weeks. Follow-up clinical data for the child (core outcome variables, medication and comorbidities) were obtained from trial sites' clinic notes closest to the follow-up timepoints."

4b-i) Report if outcomes were	(self-)assessed through	online questionnaires
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Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

subitem not at all important

essential

Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"After providing consent, participants were given baseline questionnaires to complete in clinic or at home and return to the trial co-ordinating centre (freepost envelope provided). A link to an online version of the questionnaire was also provided so parents could choose their preferred completion mode."

"At 4 and 12-months post-randomisation, the trial centre sent follow-up questionnaires both electronically and in hardcopy for participants to choose preferred completion method. Telephone and text reminders were sent if questionnaires were not returned within 2 weeks. Follow-up clinical data for the child (core outcome variables, medication and comorbidities) were obtained from trial sites' clinic notes closest to the follow-up timepoints."

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention.(Not a required item – describe only if this may bias results)

subitem not at all important

essential

Does you	r paper	address	subitem	4b-ii?
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Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable - participants were recruited from their child's hospital

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).

subitem not at all important

essential

Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Trial arms:

Control arm: Children of control arm participants continued to receive standard clinical care as provided by the study site.

Intervention arm: In addition to standard care, those allocated to the intervention arm were given free unlimited password-protected access to the website.

Website content was written by health professionals supported by a research assistant. The health professionals included: 13 rheumatologists, four rheumatology nurse specialists, two clinical psychologists, an occupational therapist, an ophthalmologist, two physiotherapists, a podiatrist and a social worker. A website consultant designed the site for layout, usability, acceptability, and interactive features.

The resulting prototype website was tested by seven parents and eight health professionals (four rheumatologists, two rheumatology nurse specialists, one physiotherapist, one clinical psychologist), to evaluate usability, navigation, structure, layout and content. Small changes were made to the website after this assessment.

Over the course of the website development but prior to trial commencement, the website was reviewed and updated to ensure user interfaces and content were current. The website is device adaptive, so suitable for use on computer, tablet and smartphone.

The website has two main components:

- 1. information about JIA and its treatment. This comprises sections about: cause; diagnosis; JIA types and symptoms; how JIA changes with time; possible complications; the rheumatology team; everyday life, available treatments.
- It also includes videos of health professionals explaining JIA and its treatment plus video testimonials from parents about living with and caring for JIA as a family.
- a JIA toolkit, based on cognitive-behavioural therapy which includes: psycho-education about thoughts, feelings, and behaviour following a diagnosis; cognitive re-structuring techniques to challenge unhelpful thinking to promote coping with JIA; problem-solving skills to promote coping with adherence issues and stressful events; strategies to promote effective communication with family members and the health care team; and pain management techniques including cognitive re-structuring, relaxation, distraction, and pacing.

The toolkit includes a number of downloadable resources: problem-solving sheet; thought diary; breaking negative thought cycle sheet; reward chart; procedure contract template and certificate; visual timetable; audio relaxation sessions for children and adults."

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

5

subitem not at all important

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nt

Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The "JIA website for Parents" site was designed following [14]:

- a) a review of the literature on parents' experiences of having a child with JIA
- b) a review of websites that included information about JIA
- c) a focus group with six parents to ask their views on what should be included in the website
- d) two focus groups with a total of 12 healthcare professionals (HCPs) six rheumatologists, five rheumatology nurse specialists, one clinical psychologist - to ask their views on what should be included in the website

Website content was written by health professionals supported by a research assistant. The health professionals included: 13 rheumatologists, four rheumatology nurse specialists, two clinical psychologists, an occupational therapist, an ophthalmologist, two physiotherapists, a podiatrist and a social worker. A website consultant designed the site for layout, usability, acceptability, and interactive features.

The resulting prototype website was tested by seven parents and eight health professionals (four rheumatologists, two rheumatology nurse specialists, one physiotherapist, one clinical psychologist), to evaluate usability, navigation, structure, layout and content. Small changes were made to the website after this assessment.

Over the course of the website development but prior to trial commencement, the website was reviewed and updated to ensure user interfaces and content were current."

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

subitem not at all important

essential

Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Over the course of the website development but prior to trial commencement, the website was reviewed and updated to ensure user interfaces and content were current."

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

3

subitem not at all important essential

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Website content was written by health professionals supported by a research assistant. The health professionals included: 13 rheumatologists, four rheumatology nurse specialists, two clinical psychologists, an occupational therapist, an ophthalmologist, two physiotherapists, a podiatrist and a social worker. A website consultant designed the site for layout, usability, acceptability, and interactive features.

The resulting prototype website was tested by seven parents and eight health professionals (four rheumatologists, two rheumatology nurse specialists, one physiotherapist, one clinical psychologist), to evaluate usability, navigation, structure, layout and content. Small changes were made to the website after this assessment."

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

5 subitem not at all important essential

Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable to this study

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

3

subitem not at all important

essential

Does your paper address subitem 5-vi?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The website is not publicly available so this is not applicable

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

5

subitem not at all important essential

Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"those allocated to the intervention arm were given free unlimited password-protected access to the website"

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and - if computermediated communication is a component - whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

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subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The website has two main components:

- 1. information about JIA and its treatment. This comprises sections about: cause; diagnosis; JIA types and symptoms; how JIA changes with time; possible complications; the rheumatology team; everyday life, available treatments.
- It also includes videos of health professionals explaining JIA and its treatment plus video testimonials from parents about living with and caring for JIA as a family.
- a JIA toolkit, based on cognitive-behavioural therapy which includes: psycho-education about thoughts, feelings, and behaviour following a diagnosis; cognitive re-structuring techniques to challenge unhelpful thinking to promote coping with JIA; problem-solving skills to promote coping with adherence issues and stressful events; strategies to promote effective communication with family members and the health care team; and pain management techniques including cognitive re-structuring, relaxation, distraction, and pacing.

The toolkit includes a number of downloadable resources: problem-solving sheet; thought diary; breaking negative thought cycle sheet; reward chart; procedure contract template and certificate; visual timetable; audio relaxation sessions for children and adults."

5-ix) Describe use paramete

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

subitem not at all important

essential

Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"those allocated to the intervention arm were given free unlimited password-protected access to the website"

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

5

subitem not at all important essential

Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

there was no human involvement - the intervention was delivered only by website

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5-VI) Report	anv	$nr \cap m$	ntc/ra	amina	larc	LICAC
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Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 - generalizability).

subitem not at all important

essential

Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

no prompts/reminders were given to use the website

5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

subitem not at all important essential

Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable - there were no cin-interventions

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"After providing consent, participants were given baseline questionnaires to complete in clinic or at home and return to the trial co-ordinating centre (freepost envelope provided). A link to an online version of the questionnaire was also provided so parents could choose their preferred completion mode."

"Trial Measures (See Table 1).

Parents provided demographic data including age, gender, educational level and relationship

The primary outcome was parenting stress at 4-months post randomisation, measured with the Pediatric Inventory for Parents (PIP)[15], which assesses difficult events that parents may face. Respondents answer two questions for each event - how often it occurred in the past 7 days and how difficult it was for them.

Secondary outcomes were:

- Parenting stress at 12 months post randomisation using the PIP.
- Parent mood, assessed with the Hospital Anxiety and Depression Scale (HADS)[16].
- Parent confidence in managing their child's arthritis, assessed with the Parent's Arthritis Self-efficacy Scale (PASE)[17].
- Parent effectiveness in managing their child's healthcare, assessed using the Effective Consumer Scale Adapted (ECS17-A)[18]. The original scale developed for adults with musculoskeletal disease was adapted to refer to how parents manage their child's disease.
- Parent satisfaction with healthcare, assessed with the Client Satisfaction Questionnaire (CSQ)[19].
- A proxy measure of the child's HRQoL was assessed with the Child Health Questionnaire 50-item parent version (CHQ-PF50)[20].

Process measures on website usage and parent coping and beliefs about their child's illness (Brief COPE[21] and Brief Illness Perception Questionnaire[22] respectively) were collected but will be reported separately from the current paper, which focuses on the trial outcomes.

Child data: Information about participants' children with JIA (gender; age; JIA subtype; date of diagnosis; core outcome variables (number of inflamed and limited joints, erythrocyte sedimentation rate, Child Health Assessment Questionnaire, parent global rating, physician global rating)[23]; medication; and any related comorbidities at the time of recruitment were gathered by the clinical sites and sent securely to the trial co-ordinating centre. Follow up:

At 4 and 12-months post-randomisation, the trial centre sent follow-up questionnaires both electronically and in hardcopy for participants to choose preferred completion method. Telephone and text reminders were sent if questionnaires were not returned within 2 weeks. Follow-up clinical data for the child (core outcome variables, medication and comorbidities) were obtained from trial sites' clinic notes closest to the follow-up timepoints."

		question	naires wer	e designe	d/deployed	d for online use [9].
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential
Does your paper address su Copy and paste relevant sections fro						
his is described in Table 1						
This is described in Table 1 Sa-ii) Describe whether and defined/measured/monitore Describe whether and how "use" (inclogins, logfile analysis, etc.). Use/aceported in any ehealth trial.	how "us d	ensity of u	se/dosage) was defi	ned/meas	ured/monitored

The current manuscript reports the trial outcomes. Another manuscript is being prepared that reports the process evaluation, including website usage.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

subitem not at all important

essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

The current manuscript reports the trial outcomes. Another manuscript is being prepared that reports the process evaluation, including qualitative feedback.

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

There were no changes to trial outcomes after the trial commenced.

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

5

subitem not at all important essential

Does your paper address subitem 7a-i?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Both parents were invited to participate, therefore sample size calculation allowed for 'clustering' by household. The power calculation was based on the PIP primary outcome measure, assessed at 4 months post-randomisation. Standard deviations on the PIP frequency (PIP-F) and difficulty (PIP-D) scales were expected to be 25 [15]. Therefore 85 households per trial arm was considered adequate to detect a mean difference of 10 points with 80% power and 5% significance level, representing a medium effect size. This allowed for clustering by household, assuming an intra-cluster correlation of 0.5. Allowing for a 15% drop out, 100 households per trial arm (200 total) were needed."

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable - interim analyses not performed

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To minimise selection bias, participants were randomised by the trial co-ordinating centre after receipt of the completed baseline questionnaire. Blocked randomisation per site was performed using computer generated randomisation sequences. "

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To minimise selection bias, participants were randomised by the trial co-ordinating centre after receipt of the completed baseline questionnaire. Blocked randomisation per site was performed using computer generated randomisation sequences."

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Blocked randomisation per site was performed using computer generated randomisation sequences."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Parents were invited to participate by their child's rheumatologist when attending a clinic appointment with their child. Interested parents had time to consider participation and opportunities to ask questions before providing written consent to site research staff."

"To minimise selection bias, participants were randomised by the trial co-ordinating centre after receipt of the completed baseline questionnaire. Blocked randomisation per site was performed using computer generated randomisation sequences."

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn't

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

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subitem not at all important	0	0	0	0	0	essentia

Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Allocation was concealed from clinical teams however, after allocation, it was not possible to blind the trial co-ordinator as the follow-up questionnaires contained additional questions about the website for intervention arm participants. Other members of the investigating team were blind to trial arm allocation. Participants were requested not to inform their child's clinicians of their trial arm allocation."

11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

subitem not at all important

essential

Does your paper address subitem 11a-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable. There was only one intervention - the website - so it was clear to all participants whether or not they had received the intervention

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address	CONSORT	subitem	11b? *
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Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - there was only one intervention

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Outcomes were compared using multi-level modelling with a random effect of household, and adjusting for the variable at baseline and any parent and child demographic characteristics that differed between trial arms. We explored the main effects of time, trial arm and their interaction, by entering trial arm, time, and the interaction between trial arm and time as fixed effects, using restricted estimate maximum likelihood method. Significant interaction terms were interpreted as indicating differential treatment effectiveness and explored with post hoc tests. Hedge's g was calculated for effect sizes of differences between trial arms at each follow-up."

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 12a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Missing value analysis, examined item-level missing data and used scale authors' rules for dealing with missing data, where provided. If rules were not available, mean imputation within a scale was used when ≥50% of scale items were available. Little's missing completely at random test was conducted to indicate the appropriateness of further imputations. If levels of missing data on any scale or item were >10%, multiple imputation was conducted (m=10). Data from all time points (baseline, 4-months and 12-months) were used to predict missing data, but the three time-points were imputed separately and only for participants who provided data at that time-point. Resultant databases were analysed separately, then Rubin's rules [24, 25] were utilised to combine the results from the 10 datasets. Responders (those who completed at least one follow-up) were compared with non-responders on baseline characteristics using logistic regressions."

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Significant interaction terms were interpreted as indicating differential treatment effectiveness and explored with post hoc tests."

"Outcomes were compared using multi-level modelling with a random effect of household, and adjusting for the variable at baseline and any parent and child demographic characteristics that differed between trial arms "

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval						
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Ethical approval. Approval obtained from Health Research Authority London Bridge Research Ethics Committee, reference 13/L0/0288"

x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

subitem not at all important essential

Does your paper address subitem X26-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Parents were invited to participate by their child's rheumatologist when attending a clinic appointment with their child. Interested parents had time to consider participation and opportunities to ask questions before providing written consent to site research staff. If their child with JIA was aged 8-12 years, the child's assent was obtained for their demographic and clinical data to be collected for the research."

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

subitem not at all important

essential

Does your paper address subitem X26-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable - the intervention was website only and we did not include other aspects such as a hotline

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Baseline questionnaires were returned by parents of 208 children ("households"). Five protocol violations were identified, leaving a final sample of 203 households, 100 randomised to intervention and 103 to control arm (Figure 1). Follow-up questionnaires were completed by 133 (65.5%) households at 4 months and 124 (61.1%) at 12 months."

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Baseline questionnaires were returned by parents of 208 children ("households"). Five protocol violations were identified, leaving a final sample of 203 households, 100 randomised to intervention and 103 to control arm (Figure 1). Follow-up questionnaires were completed by 133 (65.5%) households at 4 months and 124 (61.1%) at 12 months." Participants did not give reasons for not returning follow-up questionnaires.

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

subitem not at all important

essential

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is reported in Figure 1

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Between February 2016 and October 2018, 717 parents were assessed for eligibility and 326 consented to take part."

"Follow up:

At 4 and 12-months post-randomisation, the trial centre sent follow-up questionnaires"

14a-i) Indicate if critical "secular events" fell into the study period

Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"

subitem not at all important

essential

Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable - no such events occurred in the study period

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable - the trial was not stopped early.

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

These data are reported in Table 2

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

subitem not at all important

essential

Does your paper address subitem 15-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Age, education and gender are reported in Table 2.

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple "denominators" and provide definitions

Report multiple "denominators" and provide definitions: Report N's (and effect sizes) "across a range of study participation [and use] thresholds" [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants "used" the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define "use" of the intervention.

subitem not at all important

essential

Does your paper address subitem 16-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Multiple imputation was performed so each analysis contains the full sample size.

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

3

subitem not at all important essential

Does your paper address subitem 16-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Analyses were on an intention-to-treat basis."

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

These data are reported in Table 3 and Figures 2 and 3.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

> 1 5

subitem not at all important

essential

Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - the current manuscript reports the trial outcomes. A separate manuscript is being prepared that reports the trial process evaluation.

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - the outcomes are continuous measures

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - we did not conduct subgroup analyses

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

subitem not at all important

essential

Does your paper address subitem 18-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - the current manuscript reports the main trial outcomes; subgroup analyses have not been conducted.

19) All important harms or unintended effects in each group

(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subi

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - none to report

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

5

subitem not at all important

essential

Does your paper address subitem 19-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - none experienced.

19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

3

subitem not at all important essential

Does your paper address subitem 19-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - the current manuscript reports the main trial outcomes. Another manuscript is being prepared to report the process evaluation that will include qualitative feedback.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

subitem not at all important essential

Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"This RCT evaluated the "WebParC" website for parents of children with JIA. To our knowledge, this is the first website for parents of children with JIA that has undergone evaluation in a randomised controlled trial. The website was found to be successful in reducing child illness-related parenting stress and also promoted a greater improvement in parents' self-efficacy in managing children's symptoms."

22-ii) Highlight unanswered new questions, suggest future research						
Highlight unanswered new questions,	suggest	future rese	earch.			
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential
Does your paper address subitem 22-ii? Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study "The primary target of WebParC was parenting stress rather than mental health; using online approaches to support the mental health of parents of children with JIA may require a greater focus on parents' psychological well-being than we were able to achieve in WebParC."						
20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses						
20-i) Typical limitations in ehealth trials Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events. 1 2 3 4 5 subitem not at all important O O O O essential						

Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Limitations of the study, in common with interventions of this type, include that it was not possible to blind participants to trial arm allocation. Although requested not to inform their child's clinicians of their allocation, it is not possible to know if all participants followed this request. A proportion of parents who consented to participate in the trial did not return the baseline questionnaire and were therefore not randomised. The follow-up response rates were also lower than expected. Parents may have forgotten or not prioritised questionnaire completion; when reminders and a small incentive were introduced mid-trial, rates of baseline and follow-up questionnaire return improved. Another possibility is that although parents consented to the trial when they were in clinic, taking part in research about their own well-being, rather than their child's, was not a priority for them. Parents who did not return the baseline questionnaire may also have been reluctant to answer detailed questions about their own and their child's wellbeing. These issues will need to be considered in future studies of this type.

In common with other research[34], fathers were less likely to participate, which occurred in this trial because they were less likely than mothers to attend the clinic. It was not possible to establish whether non-participating fathers may have been given access to the website by participating partners. The small number of cases where both parents participated meant we were unable to cluster by household in our analyses.

Primary analyses with the PIP scales utilised a P<.05 value for significance as per the protocol. For secondary analyses on additional scales we did not adjust the p-value of <0.05 to allow for multiple testing so caution while interpreting should be taken. It is notable however, that the pattern of our findings, even where not statistically significant, were mostly in the direction favouring the Intervention arm therefore it is unlikely that our significant findings reflect type I error."

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to	other p	opulations
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Does your paper address subitem 21-i?

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

essential

subitem not at all important

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"In conclusion, this intervention shows potential value for reducing illness-related parenting stress. Online interventions should be a priority as they are low cost, easy to access, replicable and can offer a preventative approach to a large number of parents."

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

subitem not at all important essential

Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable - we did not include prompts and have not recommended changes outside the RCT setting.

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Trial registration: International Standard Randomized Controlled Trial Number (ISRCTN): 3159730; http://www.isrctn.com/ISRCTN13159730."

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Full trial protocol available from corresponding author."

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Funding

This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-1013-32005) and the UCLH Charity, Shipley/Rudge Fund. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. LRW is additionally supported by grants from NIHR (to the NIHR Biomedical Research Centre at GOSH), Versus Arthritis (20164, 21593) and UKRI Medical Research Council (MR/R013926/1)."

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

subitem not at all important

essential

Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Conflicts of Interest None declared"

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